Massachusetts Department of Public Health
Division of Epidemiology and Immunization

Tetanus, Diphtheria and Pertussis (Tdap) Vaccine

State-Supplied Tdap Vaccine Now Available for Adolescents 11–12 Years of Age

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In the spring of 2005, two formulations of tetanus, diphtheria and pertussis (Tdap) vaccine were licensed for use in adolescents and adults as a single booster dose. GlaxoSmithKline's BOOSTRIX® is approved for use in persons 10–18 years of age (http://www.fda.gov/cber/label/tdapgla050305LB.pdf). Sanofi pasteur's ADACEL™ is approved for use in persons 11–64 years of age (http://www.fda.gov/cber/label/tdapave061005LB.pdf). On June 30, 2005, the Advisory Committee on Immunization Practices (ACIP) voted to recommend the routine use of Tdap vaccines in adolescents aged 11–18 years in place of tetanus and diphtheria toxoids (Td) vaccine.

The Massachusetts Department of Public Health (MDPH) expects to begin supplying GlaxoSmithKline's formulation of Tdap vaccine (BOOSTRIX®) by mid- to late October 2005. MDPH will be able to provide state-purchased Tdap vaccine only for the routine immunization of **one** cohort of children 11–12 years of age (those entering 7th grade).

The primary objective of the adolescent pertussis booster vaccination program is to protect adolescents against pertussis. Interim ACIP recommendations for the use of Tdap vaccine in adolescents have been posted on the Center for Disease Control and Prevention's (CDC) website (http://www.cdc.gov/nip/vaccine/tdap/tdap_acip_recs.pdf). The final ACIP recommendations are expected to be available some time this fall and will be official when published in the MMWR (http://www.cdc.gov/mmwr/).

This advisory summarizes key ACIP recommendations for Tdap (single booster dose) and Td vaccines for adolescents aged 11–18 years, as well as the availability of state-supplied Tdap vaccine.

Interim Recommendations for the Use of Tdap Vaccines in Adolescents

1. Routine Tdap Vaccination in Adolescents 11–18 Years of Age.

Both of the Tdap products are considered interchangeable. A single dose of either BOOSTRIX® or ADACEL™ may be administered to adolescents, regardless of the type (manufacturer) of DTP/DTaP vaccine previously received. At the current time, Tdap is only approved for use as *a single booster* dose. More information is needed about the safety of additional doses in a series. When those data are available, additional recommendations may be made.

- Tdap should be used as a single booster dose, instead of Td vaccine, for the routine immunization of adolescents at 11–12 years of age, if they have completed the recommended childhood DTP/DTaP vaccination series[1]. For recommendations for those who have not completed the childhood series, see section below in **Special Situations.**
- A single booster dose of Tdap, instead of Td, should be used for adolescents 13–18 years of age who have not yet received Td, if they have completed the recommended childhood DTP/DTaP vaccination series.

  (Please note, these two groups above are the <u>only</u> ones for whom state-supplied Tdap vaccine is to be used.)

- Adolescents aged 11–18 years who have already received Td, but not Tdap, are encouraged to have a single dose of Tdap to provide protection against pertussis, if they have completed the recommended childhood DTP/DTaP vaccination series.[1] For recommendations for adolescents who have not completed the childhood series, see below in **Special Situations.**

Minimum Intervals between Td and Tdap Vaccines. A 5-year interval between Td and Tdap is encouraged to reduce the potential risk for local or systemic reactions. However, the ACIP did **not** define an absolute minimum interval between Td and Tdap, in order to give maximum flexibility to providers. Intervals shorter than 5 years between Td and Tdap can be used.[2] The benefits of protection from pertussis generally outweigh the risk of local or systemic reactions in settings with increased risk from pertussis (e.g., pertussis outbreaks and close contact with an infant aged <6 months). After weighing these risks and benefits, providers can decide whether or not to administer Tdap vaccine.

- If possible, providers should administer Tdap (or Td) and tetravalent meningococcal conjugate vaccine (MCV4), also known as Menactra™ (which contains diphtheria toxoid) during the same visit, if both vaccines are indicated and available.[3] The ACIP recommendations for MCV4 have been published in the MMWR (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5407a1.htm). Due to the current limitations in availability of MCV4, simultaneous administration of Tdap (or Td) and MCV4 may not be possible. For guidance on nonsimultaneous administration, see the section on this topic below in **Special Situations.**
- Tdap (or Td) should be administered with other vaccines that are indicated during the same visit when feasible. Each vaccine should be administered using separate syringes at different anatomic sites. Some experts recommend administering no more than two injections per deltoid, separated by one inch during one visit.

2. Special Situations for Tdap (single dose) and Td Use in Adolescents 11–18 Years of Age.

- **Nonsimultaneous vaccination**. There is a theoretical risk of increased rates of local or systemic reactions when two diphtheria toxoid-containing vaccines are administered within a short interval (on different days). However, limited data from pre-licensure clinical trials show some sequences of (and intervals between) Td and MCV4 to be acceptably safe.[3] If simultaneous vaccination is not feasible, inactivated vaccines can be administered at any time before or after a different inactivated or live vaccine. Problems with vaccine availability may make this a fairly common scenario for the next few years. Please note, Tdap (or Td) and MCV4 vaccines (which contain diphtheria toxoid) **can** be administered using **any** sequence.
- **Lack of Availability of either Tdap or MCV4**. If Tdap and MCV4 are both indicated for adolescents, but only one vaccine is available, the available vaccine should be administered.
- **Use of Td when Tdap is Not Available**. When Tdap is indicated, but not available, vaccine providers should administer Td if the last DTP/DTaP/DT/Td vaccine was >10 years earlier. Td can be deferred temporarily when the last DTP/DTaP/DT/Td was administered within 10 years, the adolescent is likely to return for follow-up, and it is not part of wound management. Vaccine providers should maintain a system to recall adolescents when Tdap/Td vaccination is deferred.
- **Pertussis Outbreaks and Other Settings with Increased Risk for Pertussis Transmission**. In these circumstances, providers may wish to administer a single dose of Tdap to adolescents at increased risk of exposure to pertussis or to those with high-risk contacts (e.g., infants < 6 months of age, children who are not vaccinated, pregnant women who are in their third trimester). Post-exposure antibiotic prophylaxis and other pertussis control guidelines are still indicated. Please contact the MDPH Immunization Program at 617-983-6800 for the latest guidelines on the prevention and control of pertussis, which can also be found on the MDPH website (http://www.mass.gov/dph/). At the current time, MDPH will not be able to provide Tdap vaccine for use in outbreak/exposure settings.
- **Tetanus Prophylaxis in Wound Management**. Adolescents who require a tetanus toxoid-containing vaccine as part of wound management should receive a single dose of Tdap instead of Td if they have not previously received Tdap. If Tdap is not available or was previously administered, adolescents who need a tetanus toxoid-containing vaccine should receive Td (http://www.cdc.gov/mmwr/preview/mmwrhtml/00041645.htm, Table 5).
- **History of Pertussis**. Adolescents who have a history of pertussis generally should receive Tdap according to the routine recommendations.

- **No History of DTP/DTaP/Td/Tdap Vaccination**. Adolescents who have *never* received tetanus-diphtheria-pertussis vaccination should receive a series of three vaccinations. The preferred schedule is a single Tdap dose, followed by a dose of Td ≥4 weeks after the Tdap dose and a second dose of Td ≥6 months after the first Td dose. Tdap may substitute for any *one* of the three Td doses in the series (e.g., Tdap, Td, Td). Remember, Tdap is only approved for one dose in the series.

  Adolescents who have received an *incomplete* series of DTP/DTaP/Td vaccinations should also receive a single dose of Tdap and any additional doses of Td needed to complete the series.

- **No History of Vaccination with Pertussis Components**. Adolescents who have not received pertussis vaccines but completed the recommended tetanus-diphtheria vaccination series[1] with pediatric DT or Td generally should receive a single dose of Tdap according to the routine recommendations, if they do not have a contraindication to the pertussis components.

- **Pregnancy**. If otherwise indicated, administration of Tdap to adolescents who are in the second or third trimester of pregnancy should be considered. Pregnancy is **not** a contraindication for Tdap or Td.

3. Contraindications and Precautions for Tdap/Td.

Please note some of the contraindications and precautions for Tdap are different than for pediatric DTaP vaccines.

- **Contraindications**. Contraindications for Tdap include: 1) severe allergic reaction to a vaccine component or following a prior dose of tetanus, diphtheria or pertussis vaccines[4]; and 2) encephalopathy, not attributed to another identifiable cause, ≤7 days of administration of a pertussis vaccine.

- **Precautions**. Precautions for Tdap include: 1) history of an Arthus-type reaction following a previous dose of tetanus or diphtheria vaccine; 2) progressive neurological disorder, uncontrolled epilepsy or progressive encephalopathy; 3) severe anaphylactic latex allergy (BOOSTRIX® pre-filled syringes *only*); 4) history of Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of tetanus vaccine; and 5) moderate or severe acute illness, with or without fever (temporary precaution).

  The following conditions, which are precautions for pediatric DTaP vaccine (when they occur following a dose of DTaP) are **NOT** precautions for Tdap: 1) fever of ≥105^0F, unexplained by another cause, within 48 hours of DTaP; 2) collapse or shock-like state within 48 hours of DTaP; 3) persistent, inconsolable crying lasting ≥3 hours or longer within 48 hours of DTaP; 4) convulsions, with or without fever, occurring within 3 days of DTaP; 5) history of extensive limb swelling after administration of DTaP.

  In addition, the following conditions are **NOT** precautions for Tdap vaccine: 1) stable neurologic disorder; 2) pregnancy; 3) breastfeeding; 4) immunosuppression, including human immunodeficiency virus (HIV) infection; 5) minor acute illness, with or without fever; and 6) antibiotic use.

4. Vaccine Information Statements.

An interim vaccine information statement (VIS) for Tdap has not yet been issued. When CDC approves the *interim* Tdap VIS it will be available at www.immunize.org/vis. After the official ACIP recommendations have been published, a *final* Tdap VIS will be re-published with a new date and a copy will be available at the above website.

5. Reporting of Adverse Events after Vaccination.

All clinically significant adverse events should be reported to VAERS, even if a causal relationship to vaccination is uncertain. VAERS reporting forms and information are available electronically at http://vaers.hhs.gov/ or by calling (800) 822-7967. Providers are encouraged to report electronically at https://secure.vaers.org/VaersDataEntryintro.htm.

6. **Future Considerations for Recommendations for Use of Tdap in Adults.**
   ACIP did not make a recommendation for use of Tdap among adults aged ≥19 years. Recommendations will be considered during future ACIP meetings after members have reviewed pertussis immunization strategies for adults.

7. **Interpretation of Pertussis Serology Test Results among Tdap Vaccine Recipients.**
   The pertussis serology assay performed at the Massachusetts State Laboratory Institute detects IgG antibody to pertussis toxin, one of the components of the Tdap vaccine. As such, serology results are **not** interpretable for those who have received Tdap within three years, since antibody levels may reflect either past vaccination and/or recent infection. As more data become available over the next few years, it may be possible to shorten the period (following Tdap vaccination) in which pertussis serologic test results are considered uninterpretable. If testing for pertussis is indicated for a recent Tdap recipient, a nasopharyngeal swab should be submitted for PCR and culture.

School Immunization Requirements

At the current time, Tdap is not required for entry into 7th grade. The requirement for Td at entry into this grade remains in effect. Tdap would satisfy this requirement.

Availability and Ordering of Tdap Vaccine Supplied by MDPH

In order to ensure adequate resources to maintain the universal childhood immunization program, MDPH will be able to provide state-purchased Tdap vaccine only for the routine immunization of **one** cohort of children 11–12 years old (those entering 7th grade). However, state-supplied vaccine *may* also be used for: 1) adolescents 13–18 years of age who have not yet received a Td vaccine; 2) wound prophylaxis in adolescents; and 3) pregnant adolescents.

State-supplied Tdap should **not** be used for: 1) adolescents 11–18 years of age who have already received Td vaccine; or 2) those at increased risk of exposure and in outbreak settings. Providers will need to use privately purchased Tdap for these groups.

New vaccine order forms and accountability forms have been developed. These new forms include both MCV4 and Tdap vaccine. You will receive copies of these new forms under separate cover with detailed instructions on their use.

Health plans and insurance carriers have been informed of the groups for whom MDPH will be supplying Tdap vaccine and the need for providers to purchase Tdap vaccine to augment their state-supplied vaccine. The Current Procedural Terminology (CPT®) code for both BOOSTRIX® and ADACEL™ is 90715. Please note, MDPH will continue to provide Td vaccine.

If you have questions about the recommendations for use of Tdap vaccine, school immunization requirements or the availability of state-supplied Tdap vaccine, please call the MDPH Immunization Program at 617-983-6800 or 888-658-2850.

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[1] Children should receive 5 doses of DTP/DTaP/DT before the 7th birthday; if dose 4 was administered on or after the 4th birthday, dose 5 is not needed. Children who began the tetanus-diphtheria vaccination series at aged ≥7 years require 3 doses of Td to complete the primary series.

[2] The safety of intervals as short as 2 years between Td and Tdap is supported by a Canadian study among nearly 6000 children/adolescents (available at http://www.fda.gov/ohrms/dockets/ac/05/transcripts/2005-4097t1.htm, Page 198).

[3] A pre-licensure study demonstrated that simultaneous vaccination with Td and MCV4 was acceptably safe; the safety of simultaneous vaccination with Tdap and MCV4 is inferred from this study. Td followed one month later by MCV4 was also studied and rates of local reactions were comparable to simultaneous vaccination. Other schedules of MCV4 and Td, and MCV4 and Tdap have not been studied (http://www.fda.gov/cber/label/mpdtave011405LB.pdf).

[4] BOOSTRIX® and ADACEL™ do **not** contain thimerosal. BOOSTRIX® and ADACEL™ vials do **not** contain latex. However, the BOOSTRIX® pre-filled syringes do contain latex in the tip cap and rubber plunger.